UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,759	03/03/2006	Mingdong Zhou	524012000300	7322

20583 7590 06/11/2008

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
GODDARD, LAURA B	
ART UNIT	PAPER NUMBER
1642	
MAIL DATE	DELIVERY MODE
06/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,759	ZHOU, MINGDONG	
	Examiner	Art Unit	
	LAURA B. GODDARD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to the special technical feature of a method for preventing, treating or delaying neoplasm in a mammal, which method comprises administering to a mammal an effective amount of an **ErbB-3 protein,** or functional fragment thereof, whereby an immune response is generated against said neoplasm and said neoplasm is prevented, treated or delayed.

Group II, claim(s) 1-14, drawn to the special technical feature of a method for preventing, treating or delaying neoplasm in a mammal, which method comprises administering to a mammal an effective amount of **a nucleic acid encoding an ErbB-3 protein,** or functional fragment thereof, whereby an immune response is generated against said neoplasm and said neoplasm is prevented, treated or delayed.

Group III, claim(s) 15-21, 25, 26, 34, 35, 38, 40, and 41, drawn to the special technical feature of **an isolated nucleic acid fragment**, which isolated nucleic acid fragment

comprises a sequence of nucleotides encoding: a) an extracellular domain of the ErbB-3 protein, or functional fragment thereof, comprising an amino acid sequence set forth in SEQ ID NO:2 or SEQ ID NO:3; b) an amino acid sequence comprising at least amino acid residues 24-81 of the amino acid sequence set forth in SEQ ID NO:14; or c) an amino acid sequence comprising at least amino acid residues 2-139 of the amino acid sequence set forth in SEQ ID NO:16; a plasmid comprising the nucleic acid fragment, a cell comprising the plasmid, a method for producing an extracellular domain of ErbB-3 protein comprising growing the cell, a pharmaceutical composition, vaccine, or kit comprising the nucleic acid fragment, and a combination of the fragment with an anti-neoplasm agent.

Group IV, claim(s) 22-24, 27, 28, 36, 37, 39, 42, and 43, drawn to the special technical feature of a substantially purified **protein or peptide**, which comprises: a) an extracellular domain of the ErbB-3 protein, or functional fragment thereof, comprising an amino acid sequence set forth in SEQ ID NO:2 or SEQ ID NO:3; b) an amino acid sequence comprising at least amino acid residues 24-81 of the amino acid sequence set forth in SEQ ID NO:14; or c) an amino acid sequence comprising at least amino acid residues 2-139 of the amino acid sequence set forth in SEQ ID NO:16; a conjugate comprising said protein or peptide and a facilitating agent; a pharmaceutical composition, vaccine, or kit comprising said protein or peptide; and a combination comprising said protein or peptide and an anti-neoplasm agent.

Group V, claim(s) 29-33, drawn to the special technical feature of **an antibody** which binds: to an epitope in an extracellular domain of the ErbB-3 protein, or functional fragment thereof, comprising an amino acid sequence set forth in SEQ ID NO:2 or SEQ ID NO:3; b) to an epitope in an amino acid sequence comprising at least amino acid residues 24-81 of the amino acid sequence set forth in SEQ ID NO:14; or c) to an epitope in an amino acid sequence comprising at least amino acid residues 2-139 of the amino acid sequence set forth in SEQ ID NO:16; and a pharmaceutical composition comprising said antibody.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-V appears to be ErbB-3.

However, said technical feature does not constitute a special technical feature in view Plowman et al (PNAS, 1990, 87:4905-4909) and Kraus et al (PNAS, 1989, 86:9193-9197). Plowman et al and Kraus et al teach the protein and nucleic acid sequence of ErbB-3 and identify the extracellular domain (Plowman et al, Figures 1-3; Kraus et al, Figure 3), wherein ErbB-3 comprises SEQ ID NO:2 or 3 of the instant application. Plowman additionally teaches antibodies to ErbB-3 (p. 4906, col. 1; Figure 4)

Therefore, the technical feature linking the inventions of Groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general incentive concept and restriction for examination purposes as indicated is proper.

SPECIES ELECTION

Species Election for Groups I and II

A. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: A nucleic acid encoding (Group II), a protein or peptide comprising (Group I):

a) an amino acid sequence set forth in SEQ ID NO:1 (claim 4);

b) amino acid residues 24-81 of the amino acid sequence set forth in SEQ ID NO:14 (claim 4);

c) amino acid residues 2-139 of the amino acid sequence set forth in SEQ ID NO:16 (claim 4);

d) an extracellular domain of the ErbB-3 protein comprising an amino acid sequence set forth in SEQ ID NO:2 (claim 5);

e) an extracellular domain of the ErbB-3 protein comprising an amino acid sequence set forth in SEQ ID NO:3 (claim 5);

ELECT one of a), b), c), d), or e).

The following claim(s) are generic: claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each sequence or fragment is structurally and functionally distinct.

B. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The neoplasm species are as follows: **Elect ONE neoplasm from claims 12-14.**

The following claim(s) are generic: claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The neoplasms have different etiolologies, different structures, and different functions, all of which distinguish them as different tissues that would require different reagents, method steps, and criteria for success to treat.

Species Election for Groups III-V

C. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: A nucleic acid encoding (Group III), a protein or peptide comprising (Group IV), or an antibody binding to an epitope comprising (Group V):

a) an extracellular domain of the ErbB-3 protein, or functional fragment thereof, comprising an amino acid sequence set forth in SEQ ID NO:2;

b) an extracellular domain of the ErbB-3 protein, or functional fragment thereof, comprising an amino acid sequence set forth in SEQ ID NO:3;

c) an amino acid sequence comprising at least amino acid residues 24-81 of the amino acid sequence set forth in SEQ ID NO:14; or

d) an amino acid sequence comprising at least amino acid residues 2-139 of the amino acid sequence set forth in SEQ ID NO:16.

ELECT one of a), b), c) or d).

The following claim(s) are generic: 15, 22, and 29.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each sequence or fragment is structurally and functionally distinct, and would require distinct antibodies for binding.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard/
Examiner, Art Unit 1642